4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-P-0115]

Determination That REGLAN Injection (Metoclopramide Injection, USP), Equivalent to 5 Milligrams Base/Milliliter and Equivalent to 10 Milligrams Base/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that REGLAN Injection (metoclopramide injection, USP), equivalent to (EQ) 5 milligrams (mg) base/milliliter (mL) and EQ 10 mg base/mL, was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Daniel Gottlieb, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6210, Silver Spring, MD 20993-0002, 301-796-6650, daniel.gottlieb@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is

bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to FDA's approval of an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

REGLAN Injection (metoclopramide injection, USP), EQ 5 mg base/mL and EQ 10 mg base/mL, is the subject of NDA 017862, held by Hikma Pharmaceuticals USA Inc., and initially approved on February 7, 1979 (EQ 5 mg base /mL) and May 28, 1987 (EQ 10 mg base/mL). REGLAN is indicated for the relief of symptoms associated with acute and recurrent diabetic gastric stasis, prophylaxis of vomiting associated with emetogenic cancer therapy, and prophylaxis of postoperative nausea and vomiting in those circumstances where nasogastric suction is undesirable. REGLAN may also be used to facilitate small bowel intubation in adults and pediatric patients in whom the tube does not pass the pylorus with conventional maneuvers or to stimulate gastric emptying and intestinal transit of barium in cases where delayed emptying interferes with radiological examination of the stomach and/or small intestine.

REGLAN Injection (metoclopramide injection, USP), EQ 5 mg base/mL and EQ 10 mg base/mL, is currently listed in the "Discontinued Drug Product List" section of the Orange Book.

Baxter Healthcare Corp. submitted a citizen petition dated February 1, 2022 (Docket No. FDA-2022-P-0115), under 21 CFR 10.30, requesting that the Agency determine whether REGLAN Injection (metoclopramide injection, USP), 5 mg base/mL, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the EQ 10 mg base/mL strength, that strength has also been discontinued. On our own initiative, we have also determined whether that strength was withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that REGLAN Injection (metoclopramide injection, USP), EQ 5 mg base/mL and EQ 10 mg base/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of REGLAN Injection (metoclopramide injection, USP), EQ 5 mg base/ mL and EQ 10 mg base/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list REGLAN Injection (metoclopramide injection, USP), EQ 5 mg base/mL and EQ 10 mg base/mL, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: July 7, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.
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